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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/389,318

09/03/1999

OSAMU SUZUKI

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21839

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10/15/2004

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EXAMINER

MARX, IRENE

ART UNIT

PAPER NUMBER

1651

DATE MAILED: 10/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/389,318	Applicant(s) SUZUKI ET AL.	
	Examiner Irene Marx	Art Unit 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 August 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 6, 7 and 33-37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 6-7, and 33-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

The amendment filed 8/20/04 is acknowledged. Claims 1, 6-7, and 33-37 are being considered on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 7, 31-33 and 35-37 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

No basis or support is found in the present specification for the production of 7 g/l arachidonic acid under the conditions of the claim designated invention with any strain of the genus *Mortierella*, subgenus *Mortierella* or any "section" thereof. Applicants rely on Example 2 as basis and support for at least some of the conditions. It is noted that the example is directed to one particular strain of *Mortierella* SAM 2197. However, not even the specific strain used *Mortierella* sp. SAM 2197 is identified as to "section" (Specification, page 10, lines 5-7). Please see *PurduePharma v. Faulding* 56 USPQ2d 1481 (CA FC 2000) for a discussion related to a failure to describe a claimed generic concept in the narrative portion of the specification, but rather basing support on limitations in examples.

Therefore, this material raises the issue of new matter and should be deleted.

Response to Arguments

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

Applicant argues that at page 7, line 32 through page 8, line 21 the generic concept as claimed is presented in the narrative portion of the invention. However, the only disclosure regarding productivity pertains to general statements of producing 7 g/l of arachidonic acid with *Mortierella* at page 8, line 1 at the recited conditions. However, the only microorganism suitable

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for this purpose within genus *Mortierella*, subgenus *Mortierella* is at page 8, line 26 wherein it is stated that a microorganism belonging to section Alpina is desirable for the production of arachidonic acid, for example. There is no clear written description of the generic concept of culturing any strain within the genus *Mortierella*, subgenus *Mortierella* having the property of producing 7 g/l at the recited conditions. It is of interest to note in this regard that the "section" within the subgenus *Mortierella* for strain *Mortierella* sp. SAM 2197 has not been determined. Thus the proper taxonomic placement of this strain in the context of the present invention cannot be readily assessed and cannot serve as a basis for extrapolation to strains likely to have similar properties of arachidonic acid productivity.

Therefore, applicant's arguments fail to persuade and the rejection is maintained.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 7 and 31-37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 7, 31-33 and 35-37 are vague, indefinite and confusing, since it is unclear which strains of fungi are properly classifiable as members of the genus *Mortierella*, subgenus *Mortierella* or in the "sections" enumerated. It is of interest to note in this regard that the "section" within the subgenus *Mortierella* for strain *Mortierella* sp. SAM 2197 has not been determined. Thus the proper taxonomic placement of this strain in the context of the present invention cannot be readily assessed and cannot serve as a basis for extrapolation to strains likely to have similar properties of arachidonic acid productivity.

Claim 34 is vague and indefinite in the recitation "culturing a microorganism of strain *Mortierella* sp. SAM 2197 and having resistance to a carbon source of high concentration". It is emphasized that there is one, single strain *Mortierella* sp. SAM 2197. Also, the recitation "and having resistance to a carbon source of high concentration" appears redundant in this context. It is recommended that the claim be amended to read "culturing the strain *Mortierella* sp. SAM 2197 in a medium having..."

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Response to Arguments

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

The arguments that the genus *Mortierella*, subgenus *Mortierella* are in accordance with the teachings of the specification is noted. However, the specification does not adequately disclose to one of ordinary skill in the art how to determine which strains of *Mortierella* properly fall into this taxonomic category.

Counsel indicates that the classification into "genus *Mortierella*, subgenus *Mortierella*" is disclosed in microbiological textbooks. The arguments by counsel in this regard have not been substantiated with appropriate evidence. It is well settled that arguments by counsel do not constitute evidence.

Therefore the rejection is deemed proper and it is adhered to.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 7 and 33, 35-37 are/remain rejected under 35 U.S.C. 103(a) as being unpatentable over Kyle for the reasons as stated in the last Office action and the further reasons below.

Response to Arguments

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

Applicant appears to argue that Kyle is not properly applied because Kyle does not specifically demonstrate productivity of arachidonic acid in the amount of at least 7 g/l.

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However, the only strain having demonstrated productivity herein to produce the required amount is one single strain, i.e., the strain *Mortierella* sp. SAM 2197. In addition, the rejection made is not an anticipation rejection, but rather an obviousness rejection. It is the Examiner's position that under the appropriate process conditions the strain of Kyle would reasonably be expected to have the required productivity, and applicants have not shown otherwise. Reliance on Table 4 is noted. However, the glucose concentration therein is higher than the concentration required for the invention as claimed.

From the data of record, a clear nexus or correlation is lacking between the cultivation of any strain of *Mortierella*, subgenus *Mortierella* having resistance to a carbon source of high concentration and the production of 7 g/l of arachidonic acid. All the data in the as-filed specification show is that one specific strain of *Mortierella* designated as SAM 2197 and not identified to species or to subgenus has this capacity. Moreover, the strain of Kyle clearly grew in the medium used, which at least suggests that the strain is resistant to the carbon source concentration provided.

The scope of the showing must be commensurate with the scope of claims to consider evidence probative of unexpected results, for example. In re Dill, 202 USPQ 805 (CCPA, 1979), In re Lindner 173 USPQ 356 (CCPA 1972), In re Hyson, 172 USPQ 399 (CCPA 1972), In re Boesch, 205 USPQ 215, (CCPA 1980), In re Grasselli, 218 USPQ 769 (Fed. Cir. 1983), In re Clemens, 206 USPQ 289 (CCPA 1980). It should be clear that the probative value of the data is not commensurate in scope with the degree of protection sought by the claim.

Claims 6 and 34 would be allowable upon resolution of all 35 U.S.C § 112 issues. There would have been no motivation for one of ordinary skill in the art to culture the particular strain *Mortierella* sp. SAM 2197 for the production of arachidonic acid in the manner claimed at the time the claimed invention was made.

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

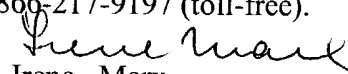
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will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (571) 272-0919. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Irene Marx
Primary Examiner
Art Unit 1651